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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,226	08/19/2003	Ashley I. Bush	0609.4810002	3164

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,226	BUSH ET AL.	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-17, and 24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4-17 and 24-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-10, drawn to a method for the identification of an agent to be used in the treatment of Alzheimer's disease and/or symptoms thereof, wherein the agent is capable of altering the production of Cu(I) by Aβ, classified in class 436, subclass 80.

II. Claims 11-17, drawn to a method for the identification of an agent to be used in the treatment of Alzheimer's disease and/or symptoms thereof, wherein the agent is capable of altering the production of Fe(II) by Aβ, classified in class 436, subclass 84.

III. Claims 24-29, drawn to a method for the identification of an agent to be used in the treatment of Alzheimer's disease and/or symptoms thereof, wherein the agent is capable of reducing the toxicity of Aβ, classified in class 436, subclass 74.

IV. Claims 30-31, drawn to a kit for determining whether an agent is capable of altering the production of Cu(I) by Aβ, classified in class 436, subclass 80.

V. Claims 32-33, drawn to a kit for determining whether an agent is capable of altering the production of Fe(II) by Aβ, classified in class 436, subclass 84.

VI. Claims 34-35, drawn to a kit for determining whether an agent is capable of altering the production of H_2O_2 by Aβ, classified in class 435, subclass 28.

VII. Claims 36-37, drawn to a method for the identification of an agent to be used in the treatment of Alzheimer's disease and/or symptoms thereof, wherein said agent is capable of inhibiting redox-reactive metal-mediating crosslinking by Aβ, classified in class 436, subclass 904.

VIII. Claim 38, drawn to a method for treating Alzheimer's disease and/or symptoms thereof comprising administering to a patient in need thereof an effective amount of an agent identified by the screening assay, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions IV/I, V/II, VI/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). The methods of Groups I, II, and III can be used independently of the kits of Groups IV, V, and VI.

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, II, III, VII, and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires alteration of Cu(I) production, which is not required by any of the other groups. Invention II requires the alteration of Fe(II) production, which is not required by any of the other groups. Invention III requires the reduction of toxicity of Aβ, which is not required by any of the other groups. Invention VII requires the inhibition of redox-reactive metal crosslinking by Aβ, which is not required by any of the other groups. Invention VIII requires the administration of an agent identified in the screening assay, which is not required by any of the other groups Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

4. Inventions IV/V/VI are unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can be used independently of each other. The administration of a treatment for Alzheimer's disease is unrelated to the kits that test for agents that affect Aβ.

5. Inventions IV, V, and VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different kits drawn to screening for agents that interact with distinctly different metal groups. The kit of Group IV is tests the effects of Cu(I) on agents. The kit of Group V is tests the effects of Fe(II) on agents. The kit of Group IV is tests for agents that alter the production of H_2O_2.

6. Invention I is unrelated to inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group I is a method for the identification of agents wherein the agent is capable of altering the production of Cu(I). The kit of Group V is tests the effects of Fe(II) on agents. The kit of Group IV is tests for agents that alter the production of H_2O_2.

7. Invention II is unrelated to inventions IV and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group II is a method for the identification of agents wherein the agent is capable of altering the production of Fe(II). The kit of Group IV is tests the effects of Cu(I) on agents. The kit of Group IV is tests for agents that alter the production of H_2O_2.

8. Invention III is unrelated to inventions IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group III is a method for the identification of agents wherein the agent is capable of reducing the toxicity of Aβ. The kit of Group IV is tests the effects of Cu(I) on agents. The kit of Group V is tests the effects of Fe(II) on agents. The kits of Groups IV and V do not determine toxicity.

9. Inventions VII and IV/V/VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the redox-reactive metal-mediating crosslinking by Aβ can be used to test Zn(II) or other redox-reactive metals that are not part of the kits of Groups IV, V, and VI. The subcombination has separate utility such as in diagnostics.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW

Brenda Brumback

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